ORAL ARGUMENT NOT YET SCHEDULED

No. 24-1188 (lead, consolidated with No. 24-1191, No. 24-1192)

In the United States Court of Appeals for the District of Columbia Circuit

American Water Works Association and Association of Metropolitan Water Agencies,

Petitioners,

v.

United States Environmental Protection Agency, and Lee M. Zeldin, in his official capacity as Administrator, United States Environmental Protection Agency

Respondents.

ON PETITION FOR REVIEW FROM FINAL RULE OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, 89 FED. REG. 32,532 (APR. 26, 2024)

BRIEF OF *AMICI CURIAE* TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT AND THE INTERNATIONAL SOCIETY FOR REGULATORY TOXICOLOGY AND PHARMACOLOGY IN SUPPORT OF PETITIONERS AND VACATUR

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), *amici curiae* state as follows:

I. Parties, Intervenors and *Amici Curiae*

Except for the following, all parties, intervenors, and amici appearing in this Court are listed in the Brief of Petitioners, American Water Works Association and Association of Metropolitan Water Agencies at page i; Brief of Petitioners National Association of Manufacturers, American Chemistry Council, and The Chemours Company FC, LLC at page iii; and the Brief of Respondents United States Environmental Protection Agency (EPA) at page i.

Additional *Amici Curiae* in support of Respondents are California, New Jersey, Arizona, Colorado, Delaware, District of Columbia, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, New York, North Carolina, Oregon, Rhode Island, and Wisconsin and Dr. Linda Birnbaum, Dr. Jamie DeWitt, Dr. Rainer Lohmann, and Dr. Jennifer Schlezinger.

Additional *Amici Curiae* in support of Petitioners are the Toxicology Excellence for Risk Assessment and the International Society for Regulatory Toxicology and Pharmacology.

II. Rulings Under Review

The agency action under review is a rule entitled "PFAS National Primary Drinking Water Regulation," 89 Fed. Reg. 32,532 (April 26, 2024).

III. Related Cases

The above-captioned case (No. 24-1188) has been consolidated with two additional petitions for review, National Ass'n of Manufacturers, et al. v. EPA, et al. (No. 24-1191) and The Chemours Co. FC, LLC v. EPA, et al. (No. 24-1192). The rule at issue has not been previously reviewed in this or any other court and Amici Curiae are aware of no other related cases within the meaning of Circuit Rule 28(a)(1)(C).

CORPORATE DISCLOSURE STATEMENT

The Toxicology Excellence for Risk Assessment ("TERA") is a non-profit, tax-exempt organization incorporated in the State of Ohio. The mission of TERA is to support the protection of public health by developing, reviewing, and communicating risk assessment values and analysis, improving risk methods through research, and educating assessors and managers and the public on risk assessment issues. TERA has no parent corporation, and no publicly held company has 10% or greater ownership in TERA.

The International Society for Regulatory Toxicology and Pharmacology is a non-profit, tax-exempt organization incorporated in Washington, D.C. The mission of ISRTP is to provide an open public forum for policy makers and scientists promoting sound toxicologic and pharmacologic science as a basis for regulation affecting human safety and health, and the environment. ISRTP has no parent corporation, and no publicly held company has 10% or greater ownership in ISRTP.

Respectfully submitted,

/s/ *Edwin Donald Elliott Jr.*
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GLOSSARY OF ABBREVIATIONS

ARA	Alliance for Risk Assessment
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
EPA	Environmental Protection Agency
FSANZ	Food Standards of Australia and New Zealand
ISRTP	International Society for Regulatory Toxicology and Pharmacology
MCL	Maximum Contaminant Level
MOA	Mode of Action
PFAS	Per- and Polyfluoroalkyl Substances
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
RfD	Reference Dose
RCC	Renal Cell Carcinoma
SDWA	Safe Drinking Water Act
TERA	Toxicology Excellence for Risk Assessment
EPA	United States Environmental Protection Agency
WHO	World Health Organization

STATUTE AND REGULATIONS

All relevant statutory and regulatory provisions referenced in this brief are contained in the EPA's addendum.

STATEMENT OF THE CASE

The statutory and regulatory background is set forth in the American Water Works Association's Statement of the Case.

INTEREST OF *AMICI CURIAE*[1]

Toxicology Excellence for Risk Assessment (TERA) is a 501(c)(3) nonprofit organization founded in 1995. TERA's mission is to assist governments, industries, and other nongovernmental organizations in evaluating the safety and risks associated with environmental chemical exposures; to develop toxicology and risk assessment values; and to educate both risk assessors and the public on environmental and public health issues.

TERA has worked on per- and polyfluoroalkyl substances (PFAS) risk assessment issues since its assistance to the State of West Virginia in 2002. Since then, it has worked for Health Canada, the United States Environmental Protection Agency (EPA), and other government and industry groups on these issues. TERA

[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from amici, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

has also participated in three unfunded international collaborations. Of particular relevance to this litigation, TERA worked with the Alliance for Risk Assessment (ARA) to develop multiple international collaborations on the safety assessment of PFAS.[2] As a result, TERA possesses a unique understanding of PFAS toxicity and extensive experience engaging with multiple entities in this field of study.

The International Society for Regulatory Toxicology and Pharmacology (ISRTP) is a 501(c)(3) scientific society formed in 1984. The purpose of ISRTP is to provide an open public forum for policy makers and scientists to promote sound toxicologic and pharmacologic science as a basis for regulation affecting human safety, health, and the environment. ISRTP is unique in its firm understanding of toxicology as it relates to regulatory policy. In 2023, ISRTP collaborated with TERA to sponsor a workshop exploring the international differences in the estimation of the safe dose[3] for perfluorooctanoate (PFOA), which at that time were

[2] The results of this work are available at https://www.tera.org/Alliance%20for%20Risk/Projects/pfoatwo.html (last accessed April 13, 2025). These comments are part of the administrative record for this rulemaking. EPA-HQ-OW-2022-0114-1606.

[3] The term "safe dose" is used to represent an exposure level estimated to be just below the population threshold for adverse effects. This population threshold is the dose-rate at which the first adverse effect, that is the critical effect, is anticipated in a sensitive group of humans. The safe dose concept is used variously by health organizations worldwide with slightly different definitions. In this brief, the term is used to describe an estimate (with imprecision spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of adverse effects during a lifetime. EPA currently uses the term "reference dose" to connote the safe dose.

more than 100,00-fold apart. This workshop was held in Washington D.C. in October 2023. Several presentations from this workshop have been published in the Journal of Toxicology and Regulatory Policy.[4]

Although the U.S. Chamber of Commerce has filed an *amicus* brief in support of Petitioners, a separate brief is necessary due to the distinct scientific expertise that TERA and ISRTP bring to bear on this matter.

Further, although an amicus brief has been filed by four scientists in support of the Respondents, no scientific *amici* have submitted a brief in support of the Petitioners. Participation by TERA and ISRTP is necessary to provide the Court with a balanced presentation of the scientific issues at stake. This balance is critical to the Court's evaluation of whether EPA's determination that the PFAS regulated in the final rule under review by this Court are "known to occur or there is a *substantial likelihood* that [they] will occur in public water systems… *at levels of public health concern*" (42 U.S.C. § 300g-1(b)(1)(A)(ii)) (emphasis added) and the Court's evaluation whether the PFAS national primary drinking water regulations promulgated by EPA based on "the best available, peer-reviewed science… in accordance with sound and objective scientific practice." 42 U.S.C. § 300g-1(b)(3)(A)(i).

[4] Available at https://isrtp.kglmeridian.com (last accessed April 13, 2025).

INTRODUCTION AND SUMMARY OF ARGUMENT

The Safe Drinking Water Act ("SDWA") gives EPA authority to establish a maximum contaminant level for contaminants in public water systems only if EPA determines the contaminant "may have an adverse effect on the health of persons" *and* "is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and *at levels of public health concern*." 42 U.S.C. § 300g-1(b)(1)(A)(i-ii) (emphasis added). Once a decision to regulate has been made, the SDWA requires EPA to set the maximum contaminant level based on "*the best available, peer-reviewed science…conducted in accordance with sound and objective scientific practice.*" 42 U.S.C. § 300g-1(b)(3)(A)(i) (emphasis added). EPA must set the regulatory standard at a level that is as close to a level at which no known or anticipated adverse health effect on the health of persons (the maximum contaminant level goal or MCLG) as is feasible (*i.e.,* can be met with available technology, taking cost into consideration). 42 U.S.C. § 300g-1(b)(4).

Determining the level at which no known or anticipated health effects occur is a scientific question that must be resolved using the best available science. 42 U.S.C. § 300g-1(b)(3)(A)(i). Thus, human health risk assessments are critical to this analysis. If these inputs are based on flawed methodologies or unsound scientific practices, the resulting MCL may be significantly distorted. The SDWA obligates

the agency to base regulatory decisions strictly on the best available science and science that can support a determination that there is a substantial likelihood of exposures at levels of public health concern, not simply any science on the record. § 300g-1(b)(3)(A)(i)-(ii); (b)(1)(A)(i)-(ii).

TERA's and ISRTP's position is that EPA's determination under the SDWA that PFOA and PFOS are found at levels of public health concern and the MCLs promulgated by EPA do not meet the requirements of the SDWA.

In summary, TERA and ISRTP believe that the extremely low exposure levels identified by EPA in its human health risk assessments do not present levels that reflect a public health concern, EPA's conclusions that both PFOA and PFOS are carcinogens are not supported by sound and objective scientific practice, and the PFAS MCLs that EPA has promulgated do not represent best available science.

TERA and ISRTP are not criticizing the various studies on PFOA and PFOS or the scientists who performed those studies. Rather, TERA and ISRTP believe that those studies do not support EPA's determination that it has met the statutory standard for establishing PFAS MCLs.

TERA and ISRTP also are not arguing that there should be no regulation of any PFAS chemicals. Rather, it is the position of TERA and ISRTP that the

maximum contaminant levels promulgated by EPA are not supported by the best available science.

ARGUMENT

I. The studies relied on by EPA do not support EPA's determinations.

As a threshold matter, to regulate contaminants under the SDWA, EPA must determine not only that a contaminant may have an adverse effect on human health, but also must determine what level of exposure to the contaminant presents a public health concern.[5] 42 U.S.C. § 300g-1(b)(1)(A)(ii). A public health concern is based on effects at the population level, not individual risk. 42 U.S.C. § 300g-1(b)(1)(C). The statutory standard for this determination is "substantial likelihood." 42 U.S.C. § 300g-1(b)(1)(A)(ii). As discussed below, the studies relied on by EPA in its final PFAS MCL rule do not support a determination that there is a substantial likelihood that there is such a risk to the U.S. population and do not support the MCLs promulgated by EPA.

[5] EPA made this regulatory determination in 2021. 86 Fed. Reg. 12,272 (Mar. 3, 2021). However, only a determination not to regulate is considered a final agency action for the purposes of judicial review. 42 U.S.C. §300g-1(b)(1)(B)(ii)(IV). A determination to regulate starts the process that culminates in a judicially reviewable final rule, like the one at issue in this litigation.

A. EPA's risk assessments for PFOA and PFOS are inconsistent with international standards.

Health organizations around the world have developed various safe doses for PFOA and PFOS. Given the choices scientists make regarding what weight to assign various studies, toxicological endpoints, and margins of safety, it is not uncommon for risk assessments to vary by a threefold margin. However, in 2023, international PFOA assessments differed from EPA's assessment by more than 100,000-fold. EPA's revised safe dose for PFOA of 0.00003 ug/kg-day (EPA, 2024)[6] remains extraordinarily low when compared with other international positions.

Due to this international disagreement, the Steering Committee of ARA proposed several related PFAS projects. One project included the development of a case study on the range of the safe doses for PFOA. This case study was discussed at an international workshop, held in conjunction with the ISRTP in October 2023.[7]

The October 2023 workshop explored reasons for EPA's extraordinary divergence from other public health agencies, including reviewing positions from ARA, the European Food Safety Authority, Food Standards of Australia and New

[6] EPA, Final Human Health Toxicity Assessment for Perfluorooctanoic Acid (PFOA) and Related Salts, No. 815R24006 (Apr. 2024), hereinafter EPA PFOA (2024).

[7] Beyond Science and Decisions Workshop XIV materials available at: https://www.tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm (last accessed April 13, 2025).

Zealand (FSANZ), the German Federal Ministry for the Environment, Health Canada, the Israel Ministry of Health, the United States EPA, and the World Health Organization.

The results of that workshop are being summarized in the first volume of the Journal of Toxicology and Regulatory Policy, in a related paper published in Regulatory Toxicology and Pharmacology (focusing on PFOA) (Burgoon, et al. 2023),[8] and in a paper submitted for publication in the Archives of Toxicology (focusing on PFOS) (Dourson et al).[9] They extensively inform this brief.

B. EPA's evaluation of the risks posed by PFOA and PFOS is inconsistent with sound and objective scientific practices.

The disparity between EPA's assessment of PFAS risk and assessments performed by other public health organizations can be explained by EPA's failure to follow sound and objective scientific practices.

For example, EPA chose to rely on human observational studies. However, such studies, while good for developing hypotheses, are not useful for establishing

[8] Burgoon, et al, 2023. Range of the Perfluorooctanoate (PFOA) Safe Dose for Human Health: An International Collaboration. Regulatory Toxicology and Pharmacology, 145, p.105502, available at https://tera.org/Alliance%20for%20Risk/Projects/Submission/Burgoon_et_al_2023.pdf (last accessed April 13, 2025).

[9] Dourson, et al (forthcoming). Range of the Perfluorooctane Sulfonic Acid (PFOS) Safe Dose for Human Health: An International Collaboration, available at https://www.tera.org/Alliance%20for%20Risk/Projects/WebDoursonetal22825.pdf (last accessed April 13, 2025).

causation due to the presence of confounding exposures and minimal exposure responses. The studies relied on by EPA also focus on identifying any biological effect rather than relevant adverse effects. As a result, few international expert bodies or even U.S. states have used EPA's choice of studies in their safety assessments.

EPA's approach fails to separate correlations from causations and is akin to observing that the sale of chocolate ice cream is associated with the incidence of outdoor crime. Even though an association between the sale of chocolate ice cream would be statistically significant in nearly any city in the U.S., it cannot be used to determine the cause of outdoor crime without first controlling for confounding exposures or seeking other explanations such as the rise in temperature. Such is the case with EPA's choice of observational studies. Statistically significant associations do not equal causation.

Nor is EPA's focus on biological responses, rather than adverse effects, appropriate for determining whether there is a substantial likelihood that PFOA and PFOS are found in public water systems at levels of public health concern. As noted by Burgoon et al. (2023):

> "[N]ot all critical effects were thought relevant to risk assessment intended to protect human health, especially in the absence of a postulated mode of action linking early necessary key events to late key events. While observed associations between PFOA blood concentrations in populations and diminished levels of serum antibodies following immunization to one or more

> specific types of vaccines might prompt additional investigation of immunosuppressive effects, the current serum concentration/antibody level data were not deemed suitable for developing a safe dose since the assessments were based upon secondary immune response (response to diphtheria and tetanus boosters), rather than primary, which contradicts the WHO immunotoxicology guidelines (derived from Van Loveren et al., 1999), as a reliable quantitative measure of immune function.

C. EPA failed to follow its own guidelines.

EPA also failed to abide by its own guidelines regarding chemical mixture assessments, cancer findings, and reference dose determinations. These failures led to EPA's unjustifiably low MCLs for the regulated PFAS and calls into question whether EPA engaged in reasoned decision-making.[10]

1. EPA failed to abide by its chemical mixture guidelines when adopting a hazard quotient approach to setting MCLs.

EPA has developed risk assessment guidelines for chemical safety assessment. Unfortunately, in the case of its assessment of PFAS, EPA often did not follow them. For example, the EPA's 1986 and 2000 chemical mixture guidelines[11] state that adding a hazard quotient (i.e., chemical exposure divided by chemical safe level) for individual chemicals is permissible, but only for a screening

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[10] "It is hard to imagine a more violent breach of [the requirement of reasoned decision-making] than applying a rule of primary conduct… which is in fact different than the rule or standard formally announced." *Allentown Mack Sales and Service Inc. v. NLRB*, 522 U.S. 359, 374 (1998) (J. Scalia).

[11] EPA, Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34014-25 (Sept. 24, 1996); EPA, Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, EPA/630/R-00/002 (Aug. 2000).

level review to quickly eliminate exposures with little to no risk. However, for final risk assessment evaluations, hazard quotients should only be added for chemicals having the same critical effect or target organ.[12] This is due to the body's resilience in the face of multiple stressors that are expected to be additive only in the same critical effect/target organ. EPA chose to regulate four of its six PFAS chemicals by adding individual hazard quotients into a hazard index (i.e., multiple hazard quotients added together for mixtures). However, the critical effect/target organs for these four chemicals are not the same, and thus according to EPA's own guidelines, cannot be added to form a usable hazard index.

2. EPA failed to follow its own guidelines in its evaluation of carcinogenicity.

EPA also did not follow its own guidelines in the evaluation of carcinogenicity. Definitive findings in two experimental animal studies are normally required for a "Likely to be Carcinogenic to Humans" cancer determination because human information most often is *not* sufficient for a credible judgment.[13] EPA made its "likely" determination with respect to PFOA without the requisite experimental

[12] EPA, Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, EPA/630/R-00/002, p. 28 (Aug. 2000) (The critical effect is the first adverse effect or its known and immediate precursor).

[13] EPA PFOA (2024), at 3-343. The reason human data is frequently unreliable is because it is difficult to obtain lengthy exposures. Additionally, confounding exposures to multiple carcinogens and uncontrolled variables (e.g., diet and smoking) make these studies generally unreliable without the more definitive animal studies.

animal data by elevating human observational studies to causal significance without due diligence to possible bias, confounding causation, or reverse causation (e.g., without controlling for reverse causation, it is impossible to determine whether elevated blood levels of PFOA in people with kidney cancer is due to a lessened ability of the kidneys to excrete PFOA because of preexisting cancer or due to PFOA exercising a carcinogenic effect on the kidneys).[14] EPA compounded these errors by failing to account for contrary human evidence and sometimes even statistically significant *reductions* in cancer.[15] This is a blatant disregard for EPA risk assessment guidelines which state:

> Conclusions regarding the strength of the evidence *for positive or negative associations* observed, as well as evidence supporting judgments of causality, should be clearly described. In assessing the human data within the overall weight of evidence, determination about the strength of the epidemiologic evidence should clearly identify the degree to which the observed associations *may be explained by other factors, including bias or confounding*.[16]

Indeed, the scientific paper relied upon by EPA to reach the conclusion that PFOA is a likely human carcinogen states: "It remains unclear whether PFOA or other PFAS are renal carcinogens or if they influence risk of renal cell carcinoma

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[14] Radhika Dhingra et al., A Study of Reverse Causation: Examining the Associations of Perfluorooctanoic Acid Serum Levels with Two Outcomes, 125 Env't Health Persp. 416-21 (2017), available at https://ehp.niehs.nih.gov/doi/10.1289/EHP273 (last accessed April 13, 2025). 181/; Boston, et al., *infra* note 18.

[15] EPA PFOA (2024) at 3-288.

[16] EPA, Guidelines for Carcinogen Risk Assessment, EPA/630/P-03/001F (Mar. 2005), at 2-4 (hereinafter EPA Carcinogen Risk Assessment Guidelines).

(RCC) at concentrations observed in the general population."[17] Recently, a published paper confirmed that the paper cited by EPA fails to support a finding that PFOA is carcinogenic by stating that "while gaps remain in the body of research, more recent epidemiological findings support that there is no causal relationship between PFOA exposure and kidney cancer or thyroid disease."[18]

Moreover, EPA applied a linear approach to the already elevated causal findings to produce an extraordinary cancer slope factor of 29,000 – unheard of in any other cancer evaluation, with the possible exception of dioxin. This judgment of linearity is generally made for a chemical when scientifically plausible, such as where the mode of action is known to cause mutations. Linearity can be evoked when the mode of action is not known, but only if the chemical is *not* mutagenic as per EPA's cancer guidelines:

> Linear extrapolation should be used when there are [mode of action] data to indicate that the dose response curve is expected to have a linear component below the [Point of Departure]. Agents that are generally considered to be linear in this region include:
>
> - agents that are DNA-reactive and have direct mutagenic activity….

[17] Shearer et al. Serum concentrations of per- and polyfluoroalkyl substances and risk of renal cell carcinoma. Journal of the National Cancer Institute 113: 580-587, available at http://dx.doi.org/10.1093/jnci/djaa143 (last accessed April 13, 2025).
[18] Boston C, Keck S, Naperala A and Collins J (2025) The evolution of PFAS epidemiology: new scientific developments call into question alleged "probable links" between PFOA and kidney cancer and thyroid disease. *Front. Public Health* 13:1532277, available at https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2025.1532277/full (last accessed April 13, 2025).

> When the weight of evidence evaluation of all available data are insufficient to establish the mode of action for a tumor site *and* when scientifically plausible based on the available data, linear extrapolation is used as a default approach, because linear extrapolation generally is considered to be a health-protective approach.[19]

However, EPA used a linear approach for PFOA despite that fact that studies show that PFOA *is not mutagenic* and there is no other evidence that linearity is scientifically plausible.[20] Thus, EPA's choice of linearity for PFOA is not consistent with its own guidelines.

Finally, EPA relied on a novel approach to mode of action evaluation proposed by the International Agency for Research on Cancer referred to as Key Characteristics of Carcinogens. This is not part of EPA's guidelines and has been severely critiqued because these characteristics alone can lead to misclassification of chemicals as carcinogens and many known carcinogens to not exhibit them.[21]

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[19] EPA Carcinogen Risk Assessment Guidelines, at 3-21.
[20] EPA PFOA (2024), at 3-295.
[21] Richard A. Becker et al., *Beyond Key Characteristics of Carcinogens: An Archetypal MOA-Based Evidence System for Hypothesis Testing to Advance Carcinogen Risk Assessment*, J. Toxicology & Regulatory Policy (forthcoming).

3. EPA disregarded multiple guidelines when developing its reference dose.

The most cavalier disregard of EPA guidelines was the agency's development of its reference dose (RfD), which is generally used in multiple regulations. Here EPA:

- Elevated human observational studies on immune effects to causal significance, similar to its findings for cancer, but in this case without the actual data nor integration of experimental animal findings at much higher doses that would have suggested otherwise,
- Classified an increase in total cholesterol from a human observational study as adverse when a human clinical study showed the opposite effect: a decrease. [22] In that study, PFOA was given over 6 weeks as a cancer chemotherapeutic agent at doses up to 1,200,000,000 ng (compare to EPA's PFOA MCL of 4 ng). Yet no adverse effects were observed.
- Judged that decreased birth weight was a critical effect based on a study by Wikstrom et al. (2020) even though effects in that study, as in other studies, showed no evidence of a dose-response relationship. [23]

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[22] Mauro Convertino et al., *Stochastic Pharmacokinetic Pharmacodynamic Modeling for Assessing the Systemic Health Risk of Perfluorooctanoate (PFOA)*, 163 Toxicol. Sci. 293 (2018).

[23] EPA PFOA (2024) at page 3-222 (noting that seven of 15 studies showed an *inverse association* between PFOA exposure and low birth weight and that *none* of

As noted by Burgoon, et al. (2023), the scientific evidence supporting identification of risk based on effects on vaccine response is similarly weak:

> [I]t was unclear whether small decreases in antibody response to vaccines are clinically significant because vast inter- and intra-individual human variability in natural vaccine response exists. This variability precludes any definitive statement in the choice of this endpoint as the critical effect. Recently, a SciPinion panel (2023, also published as Garvey et al., 2023) on immunotoxicity of PFOA suggests that the vaccine threshold of 0.1 IU/ml was not helpful for risk assessment since it is a surrogate of protection and basic immunity is presumed at even lower antibody concentrations (WHO, 2009), most recently 0.01 IU/ml.

These failures to follow sound and objective scientific practices call into question whether EPA's PFAS MCLs meet the requirements of the SDWA.

II. EPA's interpretation of its SDWA authority is not the best reading of the statute.

To regulate a contaminant under the SDWA, EPA must demonstrate that a contaminant (1) "may have an adverse effect on the health of persons" and (2) "is known to occur or there is a *substantial* likelihood that it will occur… *at levels of public health concern*." § 300g-1(b)(1)(A)(i-ii)(emphasis added).

EPA would have courts interpret these provisions in a manner that renders the "substantial likelihood" standard meaningless and places excessive reliance on the

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the 5 high confidence studies (Eick et al., 2020; Wikström et al., 2020; Sagiv et al., 2018; Shoaff et al., 2018; Bach et al., 2016) showed *any* evidence of exposure-response relationships between PFOA exposure and birth weight.

word "may" to avoid demonstrating actual adverse health effects. This sleight of hand is achieved by elevating the statute's purpose over its text. *See* EPA Brief, at 38 ("In keeping with *the health protective nature of the Act*, these first two criteria [substantial likelihood of occurrence and adverse health effects] are not onerous.") (emphasis added); EPA Brief, at 61 ("In keeping with SDWA's *health protective focus*, this threshold [adverse health effects] is not onerous; it does not require definitive proof, but rather a reasonable *possibility* of adverse health effects) (emphasis added); *id.* (arguing that the assumption of dose-additivity is justified because it is a "health-protective" approach).

Purposivism endorses the concept that a judge may interpret a statute to advance its purpose, even if the resulting interpretation goes beyond the authorities granted by the text. As then Judge Kavanaugh pointed out in his review of Judging Statutes, purposivism is a consequence of *Chevron* deference. *See* Brett M. Kavanaugh, *Fixing Statutory Interpretation*, 129 Harv. L. Rev. 2118 (2016). In *Loper Bright*, the Supreme Court recently overturned *Chevron,* rejecting such a "purposive" approach to statutory interpretation. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024). As such, this Court should reject an interpretation of the statute that elevates the purpose over the text to eliminate the need for actual data to support a determination that there is a "substantial likelihood" of occurrence and eschew the need to explain how actual adverse health effects can be caused by a contaminant to

support a determination that a contaminant "may present adverse health effects." 42 U.S.C § 300g-1(b)(1)(A)(i-ii). Following *Loper Bright*, this Court must base its interpretation of the statute on its text, not its purpose. *Loper Bright,* 603 U.S. at 443, n.6 (2024) (Justice Gorsuch, concurring). At the heart of SWDA's text is the requirement that all scientific determinations be based on the best available science and levels of public health concern must be based on a "substantial likelihood" of risk. 42 U.S.C § 300g-1(b)(3)(A)(i)-(ii); (b)(1)(A)(i)-(ii). Those mandates cannot be circumvented by diluting the statute's science-based requirements through purposivism.

The statutory standards for regulating under the SDWA are not mere window dressing – they carry real weight and must be satisfied using the best available science. By enshrining them in the statutory text, Congress vested the judiciary with the responsibility to ensure their full effect. *See Loper Bright,* 603 U.S. at 395 (emphasizing the judiciary's duty "to independently interpret… statute[s] and effectuate the will of Congress" and "police the outer boundaries" of decision-making authority delegated to agencies). In fulfilling this role, courts uphold foundational administrative-law values like transparency, deliberation, and reasoned decision-making. *See Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Insurance Co.,* 463 U.S. 29, 43 (1983) (underscoring the judiciary's role in ensuring agencies do not "rel[y] on factors which Congress has not intended it to consider…

[or] offer[] an explanation for its decision that runs counter to the evidence before the agency"). The need to safeguard principles like these is especially pronounced in the context of toxic risk regulation, where agency invocation of science in decision-making can easily mask policy choices and political pressures.[24] Failure to enforce science-based statutory mandates thereby creates perverse incentives for agencies to justify improper decisions by cloaking them in an impenetrable veil of science—a phenomenon aptly termed "the science charade."[25]

Even when a statute's text and delegations of authority "implicate a technical matter, it does not follow that Congress has taken the power to authoritatively interpret the statute from the courts and given it to the agency. Congress expects courts to handle technical statutory questions." *Loper Bright,* 603 U.S. at 402.

It is particularly important for a court to ensure an agency follows the scientific standard specified in a statute, as this Court recently acknowledged in *Maine Lobstermen's Ass'n, et al. v. National Marine Fisheries Service, et al.*, 70

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[24] Emily H. Measzell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science,* 109 MICH. L. REV. 733, 744 – 48 (2011) (describing the inherent and often obscured role policy plays in evaluating science within the context of regulatory decision-making). For example, in the context of the PFAS MCL rulemaking, EPA had an incentive to label PFOA and PFOS as linear carcinogens because then the presumption is that there is no safe level and EPA could set the PFOA and PFOS MCLs at the level at which these contaminants could be reliably quantified.

[25] Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation,* 95 COLUM. L. REV. 1613 (1995).

F.4th 582 (D.C. Cir. 2023). In that case, despite the mandate in the Endangered Species Act to use the "best available scientific data" to determine whether jeopardy of an endangered species was "likely," the National Marine Fisheries Service relied on a worst-case scenario. Accordingly, the Court vacated the biological opinion for failure to meet the statutory scientific standard. *Id.* at 599 (vacating because "[the statute] requires the Service to use the best available scientific data, not the most pessimistic"). *Maine Lobsterman's Association* is merely the latest among many decisions reinforcing the notion that courts cannot simply rubber-stamp an agency's invocation of science when a statute clearly requires the use of the best available evidence to meet specific regulatory criteria.[26] Fortunately, courts "do not decide such questions blindly." *Loper Bright,* 603 U.S. at 402. "The parties and *amici* in such cases are steeped in the subject matter, and reviewing courts have the benefit of their perspectives." *Id.*

[26] *See also* Bodine, *"Best available science" and agency decision-making*, 1 Journal of Toxicology and Regulatory Policy, 1–5 (2025) (noting that a court may say "'substantial likelihood' really means 'substantial likelihood,' 'substantial' really means 'substantial," and 'danger' really means 'danger,' placing some constraints on EPA's discretion to make scientific judgments with regulatory implications"), available at https://isrtp.kglmeridian.com/view/journals/jtrp/1/1/article-p1_5.xml (last accessed April 13, 2025).

III. EPA's failure to follow best available science and sound and objective scientific practices has significant consequences.

EPA's failure to use the best available science conducted in accordance with objective scientific practices in its required cost-benefit analysis has produced a rule that places Americans at a competitive disadvantage both at home and abroad. Because the flawed human health risk assessments for PFOA and PFOS also drive other regulatory actions, the consequences of this failure extend far beyond the present rule including but not limited to use of MCLs as "applicable or relevant and appropriate requirements" (ARARs) to guide clean-ups of groundwater, which is likely to impose costs many times greater than the direct costs of complying with the MCL.[27]

[27] Under Section 121(d) of CERCLA, Superfund remedies must meet MCLGs when remediating impacted groundwater and other drinking water sources but only "where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release." 42 U.S.C. § 9621(d)(2)(A). Further, once promulgated the MCLs could be argued to be "applicable or relevant and appropriate requirements" (ARARs) that Superfund remedies must attain. *Id.* *See also* EPA, Applicable or Relevant and Appropriate Requirements (ARARs), https://www.epa.gov/superfund/applicable-or-relevant-and-appropriate-requirements-arars#tab- (In this case where most of the benefits from controlling PFAS in drinking water do not come from controlling the PFAS but are co-benefits from controlling chlorinated hydrocarbon disinfection products that result from treating drinking water with chlorine, but that are not typically found in groundwater, it is debatable, but an issue for another day, whether the PFAS MCL is properly considered "relevant and appropriate" for cleaning up groundwater.)

A. Failure to use best available science and sound and objective scientific practices has impacted the statutorily required cost-benefit analysis.

Once an MCL is proposed, EPA must conduct a cost-benefit analysis that considers the "[q]uantifiable and nonquantifiable health risk reduction benefits" associated with the MCL. 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)-(II). Because these benefits rely on scientific assessments of health outcomes, the cost-benefit analysis must also be guided by the best available science. 42 U.S.C. § 300g-1(b)(3)(A)(i).

As the Chamber of Commerce notes, the EPA's cost-benefit analysis underestimated the cost of compliance, particularly for small water systems and individuals. Chamber Brief, at 9–13. This brief further demonstrates the inadequacy of the cost-benefit analysis by showing that EPA likely overstated the health risk reduction benefits by relying on PFAS health assessments that diverge from international scientific consensus and the best available science.

EPA responds to these criticisms by stating that it is not required to adjust the MCL in light of the cost-benefit analysis and that its decision whether to do so is unreviewable. EPA Brief, at 102. But this misses the point. Petitioners challenge the agency action as arbitrary and capricious. 5 U.S.C. § 706(2)(A). Therefore, regardless of whether the cost-benefit analysis is viewed as a grant of authority or a limit on authority, it remains true that EPA's failure to consider significant, unaffordable, costs when determining whether to exercise the authority granted by

Congress to alleviate that burden fall squarely within the scope of actions that the Supreme Court considers arbitrary and capricious. *See Ohio v. Environmental Protection Agency*, 144 S. Ct. 2040, 2053-54 (2024) (failure to consider all consequences and failure to address all significant comments renders an action arbitrary and capricious); *Michigan v. EPA*, 576 U.S. 743, 752 (2015) (unless expressly prohibited to do so, an agency must consider costs to avoid arbitrary and capricious actions).

B. Overconservatism puts Americans at an economic disadvantage both domestically and internationally.

Whether EPA properly exercised its authority under the SDWA when setting PFAS MCLs has real economic consequences. Not only would excessively conservative regulation impose unnecessary costs on water suppliers and American ratepayers, but it also will create economic burdens on Americans that are not faced by persons in other countries, making America less competitive.

Given the extreme divergence between EPA's treatment of PFAS compared to those of other nations, EPA's identification of PFAS risks are likely to generate significant technical barriers to trade – an outcome fundamentally at odds with the goal of enhancing market efficiency and strengthening America's role in global trade.

While large enterprises may be able to absorb the added compliance costs (and generate economic deadweight loss in the process) small and mid-sized enterprises

may find their participation in international trade entirely precluded. Given PFAS's widespread use in a variety of industries and products, ensuring that EPA's assessment of PFAS risks are appropriately grounded in the best available science conducted in accordance with sound and objective scientific processes is essential to mitigate these regulatory trade barriers, avoid duplicative compliance burdens, and reduce the downstream costs ultimately borne by U.S. consumers.

C. EPA's flawed human health risk assessments for PFOA and PFOS are driving other regulatory actions.

EPA is relying on the Human Health Risk Assessments for PFOA and PFOS to advance other regulatory actions related to PFAS. These include the final rule adding PFOA and PFAS to the list of hazardous substances under the Comprehensive, Environmental Response, Compensation and Liability Act,[28] EPA's draft human health water quality criteria for PFAS,[29] and EPA's draft sewage sludge risk assessment for PFOA and PFOS.[30] Accordingly, overregulation and the resultant adverse consequences are expanding as a result of the analyses EPA performed for this rulemaking.

[28] 89 Fed. Reg. 39,124 (May 8, 2024).
[29] 89 Fed. Reg. 105,041 (Dec. 26, 2024).
[30] 89 Fed. Reg. 3859 (Jan. 15, 2026).

RECOMMENDATIONS

This brief draws on TERA's and ISRTP's expertise in PFAS risk assessment to help the court lift the veil of science and expose the EPA's failure to meet its statutory mandate under the SDWA. As discussed above, it is clear that EPA failed to adhere to its own guidelines and departed from established scientific best practices, resulting in an MCL rulemaking that diverges widely from international standards for PFAS toxicity. Moving forward, EPA must ensure that its regulatory decisions are grounded in the best available science, sound scientific practices, and reasoned decision-making, particularly in matters of such profound economic consequence. That goal can best be achieved through international collaboration and comprehensive engagement with the full spectrum of relevant scientific evidence, including that of the international community.

Such a collaboration will undoubtedly result in different MCL standards. For example, the three international teams convened by TERA and the ARA that independently evaluated PFOA studies determined that in those studies a mode of action was discussed only for studies of effects on the livers of rodents. They also determined that the fact that humans have very different responses the relevance of the rodent mode of action was questionable as was the use of rodent data to develop a safe dose for PFOA. The teams noted that EPA's reliance on a human study (a study of effects on immune response from the Faroe Islands) as the sole indicator of

immunotoxicity was not appropriate. After reviewing the scientific studies, the teams developed a provisional safe dose for PFOA of between 10 and 70 ng/kg body weight-day. In contrast, EPA's Human Health Toxicity Assessment for PFOA recommends a safe dose of 0.03 ng/kg for non-cancer effects.

The three international teams convened by TERA and ARA that evaluated PFOS independently concluded that, in the absence of well-defined modes of action (MOAs) for PFOS-induced effects in people, the available epidemiologic data cannot form a reliable basis for PFOS safe dose-assessments. Those teams also concluded that bioassays of PFOS in laboratory monkeys and rats provided usable dose-response information, from which serum-concentration-based points of departure were derived. After applying several, necessarily imprecise, uncertainty factors, the three groups derived PFOS safe doses that ranged, narrowly, from 20 to 100 nanograms of PFOS/kg body weight/day. In contrast, EPA's Human Health Toxicity Assessment for PFOS recommends a safe dose (reference dose) for non-cancer effects of 0.1 ng/kg.

CONCLUSION

The errors discussed above demonstrate that the PFAS MCLs produced by EPA fail to comport with the mandates in the SDWA and resulted in a rule that is arbitrary and capricious. Accordingly, this Court should vacate the rule and remand to EPA.

Dated: April 15, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7) because the brief contains 6,082 words/uses a monospaced typeface and contains 588 lines of text. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

Dated: April 15, 2025

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system on April 15, 2025. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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